IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES ex rel. STROM,

Plaintiffs,

v.

SCIOS, INC. and JOHNSON & JOHNSON,

Defendants.

No. 05-3004 CRB (JSC)

ORDER RE: DEFENDANTS RESPONSES TO PLAINTIFFS' REQUESTS FOR ADMISSION (Dkt. No. 152)

Pending before the Court are two discovery disputes regarding Defendants' responses to discovery requests. (Dkt. Nos. 149, 152). The Court has requested further briefing regarding the dispute over Plaintiffs' response to Defendants' Requests for the Production of Documents. This order only concerns the dispute over Defendants' responses to Requests for Admission ("RFA"). (Dkt. No. 152). Having considered the papers submitted by the parties, and having had the benefit of oral argument on November 9, 2011 the Court DENIES Plaintiffs' motion to deem the requests admitted.

LEGAL STANDARD

Under the Federal Rules of Civil Procedure, a party "may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." See Fed. R. Civ.

P. 26(b)(1). Federal Rule of Civil Procedure 36(a) allows a party to serve a written request seeking to have another party admit the truth of any matters within the scope of Federal Rule of Civil Procedure 26(b)(1) relating to: 1) facts, and 2) the genuineness of documents. Rule 36(a) is designed to "expedite trial by establishing certain material facts as true and thus narrowing the range of issues for trial." Asea, Inc. v. Southern Pac. Transp. Co., 669 F.2d 1242, 1245 (9th Cir. 1981). The response to a request for admission must consist of one of the following: an admission, a denial, or a statement explaining why a party is unable to admit or deny the request. "[W]hen good faith requires that a party qualify an answer or deny only a part of the matter of which an admission is requested, the party shall specify so much of it as is true and qualify or deny the remainder." Fed. R. Civ. P. 36(a)(4).

If a party contends that the response to the request for admission does not comply with Rule 36(a), then the party may "move to determine the sufficiency of an answer or objection." Fed. R. Civ. P. 36(a)(6). If the court finds that an answer does not comply with Rule 36, "the court should ordinarily first order an amended answer, and deem the matter admitted only if a sufficient answer is not timely filed." Asea, 669 F.2d at 1247. However, "this determination, like most involved in the oversight of discovery, is left to the sound discretion of the district judge." Id.

DISCUSSION

Plaintiffs argue that Defendants' responses to RFA 7, 8, 11, 12, 13 and 15 were made in bad faith and as a result Defendants should be deemed to have admitted the requests for admission. Plaintiffs' allegations of bad faith fall in two categories: 1) those admissions that were based on the plea agreement in the related criminal case, United States v. Scios, Inc., No. CR 11-461 CRB, and 2) an admission for which Defendants' response is allegedly inconsistent with a position Defendants took elsewhere in discovery. The Court addresses each argument in turn.

A. Requests Based on the Plea Agreement in the Related Criminal Case

Plaintiffs argue that Defendants' failure to unqualifiedly admit RFA 8, 11, 12, 13 and 15 was done in bad faith because the requests track the language of the joint factual

statement in the plea agreement in the related criminal case. See *United States v. Scios, Inc.*, No. 11-cr-00461 CRB, Dkt. No. 10. Therefore, Plaintiffs argue, Defendants should be deemed to have admitted the RFAs at issue. Plaintiffs rely on In re TFT-LCD (Flat Panel) Antitrust Litigation, MDL No. 07-1827, 2011 WL 3566419, at *5 (N.D. Cal. Aug. 12, 2011), in support of the proposition that this is an appropriate sanction under these circumstances.

In Flat Panel Antitrust Litigation, the court recognized an exception to the general rule that the court is limited to reviewing the form and not the substance of RFA responses pre-trial. See id. at *3. "Rule 36 does not provide for a pretrial hearing on whether the response is warranted by the evidence thus far accumulated. Instead, Rule 37(c) is intended to provide posttrial relief in the form of a requirement that the party improperly refusing the admission pay the expenses of the other side in making the necessary proof at trial." Fed. R. Civ. P. 37, Adv. Comm. Notes (1970). Nonetheless, the court found a limited exception to this rule in the rare case where a party "intentionally disregarded the obligations imposed by Rule 36(a)" and denied the very conduct that the party had admitted before the court in a plea agreement. Flat Panel Antitrust Litigation, 2011 WL 3566419, at *5.

In Flat Panel Antitrust Litigation, the defendant admitted only that "in its November 14, 2008, Plea Agreement with the United States, [defendant] agreed that, had United States v. Sharp Corporation, No. CR 080802 SI gone to trial, the United States would have presented sufficient evidence to prove this asserted fact. Otherwise, [defendant] denies this Request." Id. at *1. In so doing, the defendant sought to deny the very facts which it had pled guilty to in the plea agreement. Here, Defendants also qualified their responses to the RFAs, but they argue that qualifications were necessary to ensure that the RFA responses were consistent with the plea agreement. As is explained below, the Court finds that Defendant's responses are for the most part consistent with the plea agreement, and, where they appear inconsistent, Defendants have a good faith basis for their response. Accordingly, the "drastic remedy" imposed by the Flat Panel court is not warranted.

Request for Admission 8

This request read as follows:

> Admit that during the period from 2001 to 2008, any use of an FDA-approved drug not specified in its FDA-approved labeling was referred to as an unapproved or "off-label" use.

The relevant portion of Defendants' response:

> Defendants admit that a use not included in a drug's FDA approved labeling is an "off-label" use as that term is typically used. Defendants further admit that a use not included in a drug's FDA-approved labeling is not FDA-approved. However, Defendants deny that all people at all times used the terms in the manner suggested by the Request. Based on the United States' broad use of the term "unapproved," inasmuch as CMS, local carriers, physicians and other health care professionals approved of off-label uses as reasonable and necessary, Defendants deny that any use of an FDA-approved drug not specified in its FDA-approved labeling was "unapproved."

The relevant portion of the plea agreement, paragraph 3, stated:

> The approved use or uses for the drug were specified in the labeling approved by FDA. Any use of an approved drug not specified in its approved labeling was referred to as an unapproved or "off-label" use.

Defendants' response to this request for admission is reasonable. Their qualification of the term "unapproved" tracks the language of the plea agreement which referred only to approval by the FDA. In other words, Defendants' qualification—while perhaps extraneous—is not inconsistent with the plea agreement.

Request for Admission 12

This request read as follows:

> Admit that infusing chronic (non-acute) congestive heart failure patients with Natrecor® on a scheduled or serial basis was an unapproved, off-label use of the drug.

The relevant portion of Defendants' response:

> Defendants admit that infusing chronic (non-acute) congestive heart failure patients with Natrecor® on a scheduled or serial basis was an unapproved, off-label use of the drug to the extent that that the term "unapproved" means not approved by FDA. However, based on the United States' broad use of the term "unapproved," inasmuch as CMS, local carriers, physicians, and other health care professionals approved of such use as reasonable and necessary, Defendants deny that infusing chronic (non-acute) congestive heart failure patients with Natrecor® on a scheduled or serial basis was an "unapproved" use.

The relevant portion of the plea agreement, paragraph 12, stated:

> Infusing chronic (non-acute) CHF patients with Natrecor® on a scheduled or serial basis was an unapproved, off-label use of the drug.

As with Defendants' response to Request for Admission 8, Defendants response to Request 12 is consistent with the plea agreement for the same reasons.

Request for Admission 11

This request read as follows:

> Admit that the approved labeling for Natrecor® did not list any use other than treatment of patients experiencing acutely decompensated congestive heart failure with dyspnea (shortness of breath) at rest or with minimal activity.

The relevant portion of Defendants' response:

> Denied, inasmuch as Natrecor®'s label describes infusions of patients with congestive heart failure. See Defendants' Exhibit 1034, Pharmacokinetic and Clinical Trials sections.

The relevant portion of the plea agreement, paragraph 11, stated:

> In August 2001, FDA approved Natrecor® solely for the treatment of patients experiencing ADHF with dyspnea (shortness of breath) at rest or with minimal activity. The approved labeling for Natrecor® did not list any other use, and the drug was never approved by FDA for any other use.

Defendants' denial of this RFA appears inconsistent with the plea agreement. Defendants explain that "for purposes of completeness and accuracy, Scios feels compelled to point out that the Clinical Trials section of the label discussed trials involving patients suffering from congestive heart failure (not only patients with ADHF)." (Dkt. No. 152, p. 5). However, rather than admitting the RFA subject to the above qualification, Defendants denied it despite the fact that language in the plea agreement mirrors the language in the RFA. At the hearing, Defendants explained further that their denial was based on the fact that the language of the RFA did not precisely track the language of the plea agreement. In response, Plaintiffs agreed to amend the request to mirror the language of the plea agreement and Defendants agreed that they would admit the RFA if Plaintiffs did so.

Request for Admission 13

This request read as follows:

> Admit that the FDA-approved labeling of Natrecor® did not contain any directions for infusing chronic (non-acute) congestive heart failure patients with Natrecor® on a scheduled or serial basis.

The relevant portion of Defendants' response:

> Defendants admit that the FDA-approved labeling of Natrecor® did not contain adequate directions for use for infusing chronic (non-acute) congestive heart failure patients with Natrecor® on a scheduled or serial basis, as the term "directions for use" is defined by 21 C.F.R. § 201.5. However, as the term "directions" is used more generally, Defendants deny that the FDA-approved labeling of Natrecor® did not contain any directions for infusing chronic (non-acute) congestive heart failure patients with Natrecor® on a scheduled or serial basis.

The relevant portion of the plea agreement, paragraph 12, stated:

> Infusing chronic (non-acute) CHF patients with Natrecor® on a scheduled or serial basis was an unapproved, off-label use of the drug. The approved labeling of Natrecor® did not contain any directions for this use of Natrecor®.

And paragraph 7:

> "Adequate directions for use" meant directions under which a layperson could use a drug safely and effectively for the purposes for which it was intended. 20 C.F.R. § 2011.5.

Defendants' response to this request also appears to directly contradict the plea agreement. Paragraph 12 states that Natrecor's® label "did not contain any directions" yet their response denies that the label "did not contain any directions." The Court nonetheless does not find that this inconsistency means that Defendants responded to the RFA in bad faith such that the drastic remedy of the RFA being admitted should be imposed.

At the hearing Defendants argued that the denial that the label did not contain "any directions" is appropriate because when paragraph 12 is viewed in context it is apparent that by "any directions" the parties meant "any adequate directions for use," a term of art defined in the plea agreement. Compare No. 11-cr-461, Dkt. No. 10 at p. 2, ¶ 1(b) and p. 10, ¶ 7:1-2 with p. 12, ¶12:4-5. Scios, Inc. pled guilty to "misbranding" in violation of 21 U.S.C. section 352(f)(1), and a drug is misbranded when its label lacks "adequate directions for use," as that term is defined at 21 C.F.R. section 201.5 and section 201.128. Thus, argues Defendants, the critical question in the plea was whether there were "adequate directions for use" not "any directions for use." The Court, of course, is not in a position to evaluate what

the parties—and the district court—intended by paragraph 12 of the plea agreement. Defendants' argument, however, is not so unreasonable that the Court can find that it was made in bad faith and therefore warrants the discovery sanction sought by Plaintiffs. Instead, Plaintiffs are free to assert at trial that Defendants should be precluded from arguing that there were any directions for outpatient use on the label, either because of an estoppel based on the plea agreement, for relevance, lack of evidence, or otherwise.

Request for Admission 15

This request read as follows:

> Admit that between August 2001 and April 1, 2003, one of Scios's intended uses for Natrecor® was for infusing chronic (non-acute) congestive heart failure patients on a scheduled or serial basis.

The relevant portion of Defendants' response:

> Scios admits that, to the extent "intent" includes expectation or knowledge, at some point between August 2001 and April 1, 2003, Scios "intended" that Natrecor® be used for infusing chronic, non-acute, congestive heart failure patients on a scheduled or serial basis.

The relevant portion of the plea agreement, paragraph 14, stated:

> Between August 2001, and April 1, 2003, commencing after the approval of Natrecor®, one of Scios's "intended uses" for Natrecor® was for infusing chronic (non-acute) CHF patients on a scheduled or serial basis, thereby causing the introduction and delivery for introduction into interstate commerce of the prescription drug Natrecor®, which was misbranded in that its labeling lacked adequate directions for use.

And paragraph 7:

> "Intended use," as defined by 21 C.F.R. § 201.128, referred to the objective intent of the persons responsible for labeling the drugs.

Defendants allege that their qualification of RFA 15 was done for the same reasons as the qualification for RFA 13 – to make the response consistent with the definition of terms found elsewhere in the plea agreement. However, Defendants' limitation with RFA 15 does not simply seek to define the term "intended uses" by reference to the regulation. Instead, Defendants include their own definition of "intent" as "expectation or knowledge," which does not appear in the plea agreement. As with Request for Admission 13, the Court finds

Defendants' response does not rise to the level of bad faith warranting the severe penalty of deeming the request admitted. Indeed, it is not clear why Defendants' admission of an "expectation or knowledge" that Natrecor® be used for infusing chronic (non-acute) CHF patients on a scheduled or serial basis is materially different from its admission in the plea agreement.

Plaintiffs' other, perhaps primary, concern with Defendants' response is the qualification that "at some point" between April 2001 and April 2003, Scios, Inc. had the intent to market Natrecor® for such outpatient use rather than having that intent continuously during that period. Again, the Court agrees that there is at least some facial inconsistency between the plea agreement and Defendants' response; however, paragraph 14 is not so definitive as to Scios, Inc.'s continuous and uninterrupted intent during the relevant period that this Court could find that its response is made in bad faith and warrants a drastic discovery sanction. At bottom, the parties have a good faith dispute as to the meaning of the statement of facts in the plea agreement. That dispute may have to be resolved by the district court if Plaintiff is going to take the position that certain defense theories or arguments are precluded by the plea argument. The existence of the dispute, however, does not mean that the RFAs must be admitted and the dispute mooted.

B. Request Based on Other Discovery Responses

Request for Admission 7

This request read as follows:

> Admit that during the period that the Lash Group was providing reimbursement information regarding Natrecor® to health care providers, the Lash Group employees involved in providing such information were the functional equivalent of Scios employees.

The relevant portion of Defendants' response:

> Denied.

Defendant sought to explain this response in responding to Interrogatory 7(e):

> With respect to Request for Admission No. 7, based on the United States' broad use of the term "functional equivalent of Scios employees," Scios denies that the Lash Group employees were the functional equivalent of Scios employees in all

> material respects. As stated in Scios' contract with the Lash Group: "The relationship of the parties under this Agreement is that of independent contractors, and nothing in it shall be construed as establishing an employer-employee, joint-venture, or principal-agent relationship between the parties. Neither party shall be responsible for the acts or omissions of the other party, and neither party shall represent or obligate the other party in any way without written authority from the other party." See SCIOS 00118049-068. However, Scios notes that to the extent that there were any communications between members of the Lash Group and Scios attorneys, and for the purpose of determining whether the attorney-client privilege applies to those communications, Lash Group employees were independent contractors "who due to their relationship to the client, possess[ed] the very sort of information that the privilege envisions flowing most freely." United States v. Graf, 610 F.3d 1148, 1159 (9th Cir. 2010) (quoting In re Bieter, 16 F.3d 929, 937-38 (8th Cir. 1994); see also In re Bieter Co., 16 F.3d at 937 ("when applying the attorney-client privilege to a corporation or a partnership, it is inappropriate to distinguish between those on the client's payroll and those who are instead, and for whatever reason, employed as independent contractors"). J&J was not a party to Scios' contract with the Lash Group and therefore has no knowledge related to this Request.

Plaintiffs' allegations of bad faith with respect to this RFA do not have to do with the plea agreement. Rather, Plaintiffs contend that Defendant Scios is attempting to have it both ways, by asserting attorney-client privilege with respect to its relationship with the Lash Group based their status as independent contractors of Scios, on the one hand, and on the other hand, alleging that the Lash Group was not the functional equivalent of an employee. Defendant's argument that attorney-client privilege would apply to communications between itself and its independent contractors is consistent with the caselaw as this Court previously recognized in finding that the attorney-client privilege could extend to protect communications between Scios and its outside consultant Dr. Lipicky. (Dkt. No. 134). See United States v. Graf, 610 F.3d 1148, 1159 (9th Cir. 2010) (quoting In re Bieter, 16 F.3d 929, 937-38 (8th Cir. 1994); see also In re Bieter Co., 16 F.3d at 937 ("when applying the attorney-client privilege to a corporation or a partnership, it is inappropriate to distinguish between those on the client's payroll and those who are instead, and for whatever reason, employed as independent contractors"). Accordingly, no sanction is warranted.

CONCLUSION

Plaintiffs have agreed to amend Request for Admission 11 to track the language of the plea agreement and Defendants have agreed to admit such language. In all other respects Plaintiffs' motion to deem the disputed RFAs admitted is denied. The Court finds that some of Defendants' responses—while not precisely tracking the language of the plea agreement—are nonetheless based on a good faith dispute as to the meaning of the plea agreement and thus fall far afield of the circumstances in Flat Panel Antitrust Litigation, 2011 WL 3566419 (N.D. Cal. Aug. 12, 2011). Accordingly, Plaintiffs' request to deem certain RFAs admitted (Dkt. No. 152) is DENIED.

IT IS SO ORDERED.

Dated: November 9, 2011

Jacqueline S. Corley

JACQUELINE SCOTT CORLEY
UNITED STATES MAGISTRATE JUDGE